

In re: Simmons, *et al.*
Serial No. 10/601,241
Filed: June 20, 2003
Page 5

REMARKS

Applicants appreciate the thorough examination of the present application as evidenced by the Office Action date August 27, 2007 (hereinafter, the "Office Action"). Claims 1 and 3-21 are currently pending. Claim 2 has been cancelled.

In re: Simmons, *et al.*
Serial No. 10/601,241
Filed: June 20, 2003
Page 6

Claim Rejections Under 35 U.S.C. §112, First Paragraph, and 35 U.S.C. §101

Claims 2-6 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement, and 35 U.S.C. §101 as not supported by either an asserted utility or a well established utility based on the claims reciting a "composition for preventing cancer." Claim 2 has been cancelled and the dependency of Claims 3-6 has been amended to not refer to a cancelled claim. Thus, Applicants believe that the §112 and §101 rejections of Claims 2-6 have been obviated.

Claim Rejections Under 35 U.S.C. §103

The case law is clear with respect to obviousness. The cited references, when combined, must teach or suggest *all* the recitations of the claims, and there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. M.P.E.P. §2143. At least in view of the discussion below, the pending claims are not obvious in view of the cited references.

Claims 1-21 are rejected under 35 U.S.C. §103(a) as being unpatentable over the combination of Anzaghi et al, Jung, Yamawaki et al as evidenced by Rochat et al. *See*, Office Action, pages 4-6.

First, the Applicants wish to remind the Examiner that the present invention pertains to a liquid composition for restoring or maintaining colon functionality (not inflammation). The composition is further characterized in that, it comprises within the same formulation a non-digestible oligosaccharide, e.g., a fructooligosaccharide (CFOS), and at least one green tea catechin, e.g., epigallocatechin gallate (EGCG), which are present in a state that is useful for restoring or maintaining colon functionality. The liquid composition is further being characterized as having a pH range of from about 4.7 to about 5.0.

It is well known in the prior art that FOS are relatively stable in a neutral (pH) environment. FOS has been clinically proven to provide mild laxation and anti-diarrheal action. It is also known that green tea catechins are stable in an acidic pH environment. In particular, EGCG was found to be very stable at pH 3.0 with about 40% reduction in degradation. Conversely, at near neutral pH values as required by FOS, e.g., pH 5.0, complete degradation occurred within one week. This led the inventors to incorporate suitable antioxidants into the formulation to minimize EGCG degradation at these higher pH values. Green tea components such as EGCG have been clinically proven to increase bifido-bacteria in numbers and improve defecation habits in humans. It has thus come to the attention of the inventors that the preparation of a composition combining both a non-digestible oligosaccharide and a green tea catechin in stable condition would be useful in restoring or maintaining colon functionality. However, the challenge was to come up with a way to combine these two components within the same composition, all the while maintaining each

of them in a stable form. The invention as presently claimed is the result of the work carried out by the inventors in order to find a solution to such problem.

A. Discussion of References Cited By The Examiner

Anzaghi *et al.* provides a formulation which does not present hepatic and central toxicity problems caused by drinking wine while providing other well known benefits attributed to wine's natural constituents. The dietary supplement from wine vinasse comprises antioxidant complexes but which is exempt of ethyl alcohol. Green tea extracts may be present in such composition as free oxygen radical scavengers. The reference is silent about the presence of FOS within the same composition.

Jung discloses an anti-inflammatory health drink comprising FOS only.

Yamawaki *et al.* discloses a new piperazine derivative useful as an anti-inflammatory agent or anti-allergenic agent comprising among others conventional buffers such as citric acid. This document makes no mention of FOS and/or green tea catechin.

Rochat *et al.* discloses an anti-inflammatory pre-biotic composition comprising FOS only. No mention of green tea catechin is made.

B. Examiner's §103 Rejections

Based on the above-mentioned references, the Examiner concludes: "*It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose... [T]he idea of combining them flows logically from their having been individually taught in the prior art.*" *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie obvious*.)."

The Examiner further states "*It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant*

compositions for their known benefit since each is well known in the art for treating inflammation. This rejection is based on the well established proposition of patent law that no invention resides in combining old composition of known properties where the results obtained thereby are no more than the additive effect of the compositions, In re Sussman, 136, F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943)."

Finally the Examiner concludes: *"Therefore, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to combine the inventions of Anzaghi et al, Jung, Yamawaki et al, and Rochat et al since all of them teach compositions for treating inflammation individually in the art. Since all the compositions yielded beneficial results treating inflammation, one of ordinary skill in the art would have been motivated to make the modifications. Regarding the limitation to the amount of the components or the pH of the composition, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, which is dependent on inflammatory condition or the stability of the composition that is needed, From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention. Thus, the invention as a whole is prima facie obvious over the references, especially in the absence of evidence to the contrary."*

The Examiner is reminded that the composition of the present invention is useful for restoring and/or maintaining colon health. Therefore, it could not be said that it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition to be used for the very same purpose.

Furthermore, it is incorrect to state that the present invention is merely a result of the combination of composition of the prior art since, simply combining compositions of the prior art without any concern as to the pH of the composition would not result in the composition of the present invention which is useful for the purpose of

restoration/maintenance of the colon. Indeed, the mere combination of a composition comprising FOS with another comprising green tea catechin would result in a composition in which, depending on the pH of the composition, one of the two components would be degraded.

It can also not be said that the limitation to the amount of the components or the pH of the composition is a result of conventional working parameters which is deemed merely a matter of judicious selection and routine optimization since it is due to the pH adjustment that the coexistence of FOS and green tea catechin within the same formulation is possible. Since FOS is stable in a neutral environment and green tea catechin is stable in an acidic environment, it cannot be said that it would have been obvious for a person skilled in the art to provide in an environment having a pH ranging from 4.7 to 5.0 that would allow both of these components to be stable within the same formulation. The cited references are silent about such feature.

Therefore, it is submitted that the composition of the present invention would not have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains, since none of the references teach or merely suggest a way to combine both FOS and green tea components in a stable form within the same composition.

The Examiner will further note that Claim 1 has been amended to incorporate the presence of at least one antioxidant, as such component is also useful in preventing EGCG degradation.

In light of the above, the invention as presently claimed is new and inventive as none of the prior art references disclose:

- a composition useful for restoring and/or maintaining colon functionality; and
- a composition having a pH ranging from 4.7 to 5.0 which combines FOS and green tea catechin in a stable form.

In re: Simmons, *et al.*
Serial No. 10/601,241
Filed: June 20, 2003
Page 11

Therefore, the Examiner is requested to withdraw his rejection of the claim.

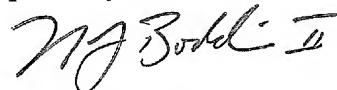
In view of the foregoing amendments and remarks, Applicants respectfully request that all outstanding rejections to the claims be withdrawn and that a Notice of Allowance be issued in due course. The Examiner is invited and encouraged to contact the undersigned directly if such contact will expedite the prosecution of the pending claims to issue. In any event, any questions that the Examiner may have should be directed to the undersigned, who may be reached at (919) 854-1400.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 50-0220 and please credit any excess fees to such Deposit Account.

Conclusion

In view of the above, it is respectfully submitted that this application is in condition for allowance, which action is respectfully requested.

Respectfully submitted,

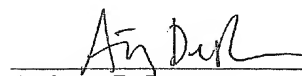


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Anthony DeRosa